



Labeling Food Production Methods and Technologies

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Labeling Food Production Methods and Technologies

I. Introduction

II. Labeling Food Production Methods and Technologies

A. Background to Food Labeling Laws and Regulations in the United States

B. Labeling for Specific Technologies and Production Methods in the United States

1. Hormones in Cows

a. Treating cows with hormones other than rBST

b. Treating cows with rBST

i. Mandatory Labeling

ii. Voluntary Labeling

2. Genetically Engineered Foods

i. Mandatory Labeling

ii. Voluntary Labeling

3. Cloned Animals

4. Farm-Raised or Wild-Caught Fish and Shellfish

5. Irradiation

6. Food Produced Organically

7. Water Fluoridation

8. Dolphin-Safe Tuna

9. Iodized Salt

10. Food Produced Abroad

11. Fruit Juice Pasteurization

12. Grass Fed Animals

13. Caffeine Content

C. Labeling Technologies and Production Methods in the European Union

1. Technologies not used or approved

2. Mandatory Labeling

D. Potential Food Labeling Rubrics

1. Distance from production method's application to consumption

2. Food technologies occurring along a continuum

E. Labeling Based on Consumer Interest

1. Labeling on the basis of consumer interest serves as a back-door way to undercut approval.

2. When people start trying to weigh the factors for food labeling, they sometimes bring in ones that make no sense.

3. Labeling may suggest that labeled foods are better or safer.

4. Consumer desires for labeling may not be based on accurate or complete information.

5. Individuals may be biased against novelty.

6. There will always be something else consumers want to know about their food.

7. Process labeling may impose unnecessary costs.

IV. Conclusion

I. Introduction

Every food has a story. Archeologists and biologists can tell food stories involving processes like evolution, domestication, and traditional breeding, and each individual serving of food has a story of its own.

The United States started as a nation of farmers. Most people lived on farms and grew their own food. Before planes, trains, and automobiles, food could not be transported from place to place as easily and quickly. Most food came from nearby, with some exceptions for specialty products like spices and flavorings.

Recently, food technologies have multiplied. From methods of production like synthetic fertilizers and factory farming, to new ways of processing and preparing food prior to consumption like chemically bleaching flour and ripening fresh fruit with ethylene gas, dramatic changes in food technology in the past century have not only increased food production immensely,¹ but also have decreased the amount people are able to know about the food they eat.

Before, if people did not grow their food themselves, they could usually trace the shorter food stories to the food producers. Now, with exceptions for things like farmers' markets, all that most people know about the food they eat is what is on the label.²

In today's complex food system, labels can reveal only some of a food's story. In the United States, Congress and the states have required food labels to bear certain information. This paper examines how the federal government in the United States makes decisions about food labeling for food processing methods.

¹ *Forgotten Benefactor of Humanity*, 279 THE ATLANTIC MONTHLY 1, 75-82 (Jan. 1997).

² See Terry Marsden, *Theorising food quality: some key issues in understanding its competitive production and regulation*, 134, in QUALITIES OF FOOD (MARK HARVEY, ET AL., EDS. (2004) (longer food supply chains ensure quality and regulate production and processing through "more formalised institutional codes (e.g. labels).").

How does the federal government – Congress, and where it has delegated authority, the FDA, USDA, and FTC – decide whether to label certain food technologies? For example, foods that are genetically modified, produced by cloning, picked while not ripe and exposed to chemicals while being transported, fumigated to reduce pathogens, covered with wax to have an extended shelf life, etc., are not required to be labeled as such. On the other hand, for food that irradiated, and fish that are farm-raised or wild-caught, labeling is mandatory.

On one level, food labeling laws are made just like all other laws, and regardless of what purpose Congress claims they are being passed for, they represent a mix of interest group maneuvering, meeting public demand, posturing about furthering safety and healthfulness, and various other things that probably make any consistency in food labeling laws surprising rather than questionable.

Similarly, although Congress has given the various agencies responsible for most food labeling decisions some instructions, and although the agencies are supposed to give reasons for their decisions, it seems that ultimately, agency labeling decisions are in many ways a black box. This makes sense: because the agencies are responsible for weighing so many different interests, which interests which ultimately predominate may be difficult to ascertain.

From hundreds of scientific articles about safety and nutrition, the preferences of food manufacturers and interested consumers, treaty obligations with regard to food imported and exported, possible ecological consequences, and social science and economics research about the effects of labels on consumer and manufacturer behavior, the sources of information that bear on whether or not a specific food technology should be labeled are legion. Even when an agency states it decided to (or not to) mandate that producers label for a food technology because of one reason, some will question this, and even claim the real reason was something else.

This paper begins with a general overview of federal food labeling regulation in the United States. It then lists various food technologies and processing methods, and discusses the federal government's labeling requirements for that technology or method of production. For comparison, decisions the European Union has made on some of these issues are summarized after those of the United States.

After describing current laws, the paper tries to draw conclusions from the labeling requirements of various technologies and food processing methods. Those conclusions take the form of two decision-making rubrics that may play a role or could play a role in making determinations about whether food processing methods should be labeled.

The first rubric suggests that food labeling decisions should take into consideration how near to consumption the food technology application takes place. For example, there may be fewer reasons to require labeling for processing that happens to seeds that then grow into plants whose fruits are harvested for consumption, than there would be for labeling processing that happens to fruits immediately before consumption.

The second rubric recognizes that other technologies, or at least, irradiation, may fall into the theory that labeling may be less helpful when a technology merely represents the newest iteration of a long series of food processing technologies, or merely the newest end of the continuum, when prior versions of the technology have not had mandatory labeling.

Finally, much of the recent academic discussion in the United States regarding food labeling has focused on whether consumers have a "right to know" things about their food. If consumer interest is a trump card, then the other factors would not matter. This paper concludes by discussing this idea, first arguing argues that the government should not mandate labeling for certain technologies based solely on consumer interest, for a number of different reasons.

II. Labeling Food Production Methods and Technologies

A. Background to Food Labeling Laws and Regulations in the United States

The FDA, USDA, and FTC all participate in regulating food labeling in the United States. The USDA regulates the labeling of meat, dairy, and egg products.³ The FDA has regulates the labeling of other foods. The FTC regulates food advertising, considered a type of labeling, and the FDA also can do so when the FTC decides not to. Some see this division of food labeling authority as problematic. A bill to consolidate the responsibility for food labeling into a single agency was proposed in Congress in 1999.⁴

Federal law mandates disclosure of at least five types of information on every food label: the name of the food, the name and place of business of the manufacturer, a statement of ingredients, the net quantity of contents, and nutrient content.⁵

Food labeling may not be “false or misleading in any particular.”⁶ “In determining whether the labeling is misleading,” the FDA shall take into account not only the “representations made or suggested” about the product but also the extent to which the labeling [] fails to reveal” material facts.⁷

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts

³ Federal Meat Inspection Act (FMIA; 21 U.S.C. 601, 607) & Poultry Products Inspection Act (PPIA; 21 U.S.C. 451, 457).

⁴ S. 1281(Durbin)/H.R. 2345 (DeLauro) Safe Food Act of 1999. S. 1281 introduced June 24, 1999; referred to Committee on Governmental Affairs. H.R. 2345 introduced June 24, 1999; referred to Committees on Agriculture and Commerce. ⁴<http://digital.library.unt.edu/ark:/67531/metacrs1226/m1/>

⁵ §403 FDCA (21 U.S.C. 343).

⁶ 21 U.S.C. § 343(a)(1).

⁷ 21 U.S.C. § 321(n) (Material facts must be disclosed under sections 403(a) and 201(n) of the act).

material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.⁸

Since the early 1970s, FDA has used this provision to require certain types of additional information in food labeling.⁹

The FDA has “generally limited the scope of the materiality concept to information about the attributes of the food itself,”¹⁰ and has required labeling “where the absence of such information may:

- (1) pose special health or environmental risks (e.g., warning statement on certain protein diet products);
- (2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or
- (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic (i.e., affects taste, color, odor, or feel), or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).”¹¹

“Disclosure of the conditions or methods of manufacturers has long been deemed unnecessary under the law. The Supreme Court reasoned in 1924, ‘When considered

⁸ 21 U.S.C. § 321(n) (emphasis added).

⁹ PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 119 (3d. ed., 2007).

¹⁰ Statement of Lester M. Crawford, Deputy Commissioner FDA, *Regulation of Foods Derived From Plants*, (June 17, 2003), available at <http://www.fda.gov/NewsEvents/Testimony/ucm161037.htm>.

¹¹ *Id.*

independently of the product, the method of manufacture is not material. The act requires no disclosure concerning it.”¹²

Originally, the purpose of food labeling laws was to prevent deception.¹³ As Congress has given agencies more authority to mandate labeling, for example, about nutrition, the purposes of food labeling have expanded. By 1938, food labeling laws aimed to communicate “essential information to enable consumers to choose foods more wisely.”¹⁴ Now, food labeling experts explain that “[g]overnment intervention in labeling in the United States has served three main purposes: to ensure fair competition among producers, to increase consumers’ access to information, and to reduce risks to individual consumer safety and health.”¹⁵

B. Labeling for Specific Technologies and Production Methods in the United States

1. Hormones in Cows

a. Treating cows with hormones other than rBST

Dairy cows have been treated with hormones for decades. For example, since the early 1940s farmers have often treated follicular cysts and anovulation in cows with gonadotropin-releasing hormone, human chorionic gonadotropin, progesterone, or combinations of these hormones.¹⁶ Milk produced by cows treated with hormones other than rBST do not have to be labeled as such.

¹² *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, n. 10 (2000), citing *U.S. v. Ninety-Five Bottles (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 445, 68 L. Ed. 1094, 44 S. Ct. 529 (1924) (referring to the Food and Drug Act of June 30, 1906, Pub. L. No. 59-384, 34 Stat. 768, precursor to the FDCA).

¹³ Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 50 (1997).

¹⁴ Degnan, *supra* note 17, at 54.

¹⁵ *Introduction*, 1, citing Susan G. Hadden, READ THE LABEL: REDUCING RISK BY PROVIDING INFORMATION (1986), in Elise Golan, et al., *Economics of Food Labeling*, AGRICULTURAL ECONOMIC REPORT NO. 793, (Jan. 2001), available at <http://www.ers.usda.gov/publications/aer793/AER793.PDF>.

¹⁶ *Management and Treatment of Dairy Cows that are Not Cycling or have Follicular Cysts*, UMass Extension, Center for Agriculture, Aug. 17, 2010, available at <http://www.extension.org/pages/11818/management-and-treatment-of-dairy-cows-that-are-not-cycling-or-have-follicular-cysts>. For example, “[t]he most utilized treatment for anovular cows in the U.S.A. is the Ovsynch protocol. This protocol utilizes GnRH, followed 7 days later with PGF2 α , and 48-56 hours later with a second GnRH, and a timed AI at 14-18 hours after the second GnRH treatment.

b. Treating cows with rBST

Recombinant bovine growth hormone, rBST, is a synthetic growth hormone “given to lactating cows to increase their milk production. As used, rbST combines with the naturally occurring bovine [growth hormone] to increase dairy cows’ milk production by up to 10 percent over cows not given the artificial hormone.”¹⁷ rBST was approved in 1994 and as of 2003, was used in about a third of the dairy cows in the United States.¹⁸

i. Mandatory Labeling

The FDA decided not to require labeling for milk from cows treated with rbST.¹⁹ The FDA explained that it made this decision because there was no significant difference between milk from cows treated with the hormone and cows not treated with the hormone.²⁰

Since the FDA did not require labeling, Vermont passed a law requiring that products from cows treated with the growth hormone be labeled.²¹ This apparently resulted from consumer concerns unique to rBST as compared to other hormones used in cows, because rBST is a genetically modified version of the natural bovine growth hormone.

Dairy manufacturers challenged this law under the first amendment and the commerce clause.²² After losing their motion for a preliminary injunction in the district court,²³ the dairy manufacturers appealed to the Second Circuit.

This protocol appears to induce ovulation in a high percentage of anovular dairy cows, but some of these cows have a subsequent short luteal phase (Gumen et al., 2003).” *Id.*

¹⁷ *International Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 632 (6th Cir. 2010).

¹⁸ David Barboza, *Monsanto Sues Dairy in Maine Over Label’s Remarks on Hormones*, N.Y. TIMES, July 12, 2003, available at <http://www.nytimes.com/2003/07/12/business/monsanto-sues-dairy-in-maine-over-label-s-remarks-on-hormones.html>.

¹⁹ *Stauber v. Shalala*, 895 F. Supp. 1178, 1188 (W.D. Wis. 1995).

²⁰ *Id.*

²¹ Vt. Stat. Ann. 6 § 2754(c).

²² *International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 70 (2d. Cir. 1996).

²³ *Id.*

The Second Circuit reversed the district court, finding both that the dairy farmers were irreparably harmed by the labeling requirement and likely to succeed on the merits.²⁴ In its analysis of the merits, the court held that the Vermont government's interest in mandating the labeling, that of satisfying consumer interest and the public "right to know," was not substantial, as required by *Central Hudson*.²⁵

The court explained that consumer interest has never been sufficient to require labeling, and that there were practical reasons why this was the case:

Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods. For instance, with respect to cattle, consumers might reasonably evince an interest in knowing which grains herds were fed, with which medicines they were treated, or the age at which they were slaughtered. Absent, however, some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.

In dissent, Judge Leval argued that "Vermont's regulation requiring disclosure of use of rBST in milk production was based on substantial state interests, including worries about rBST's impact on human and cow health, fears for the survival of small dairy farms, and concerns about the manipulation of nature through biotechnology. The objective of the plaintiff milk producers

²⁴ *Id.* at 70-73.

²⁵ *Id.* at 72-73, see *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 566 (1980).

is to conceal their use of rBST from consumers.”²⁶ In his analysis, these factors should be weighed to give “Vermont [] the right to protect its consumers by requiring truthful disclosure on a subject of legitimate public concern.”²⁷

This FDA decision was also challenged by “American consumers of commercially sold dairy products” in *Stauber v. Shalala*.²⁸ The court held that “[i]n the absence of evidence of a material difference between rbST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act.”²⁹

ii. Voluntary Labeling

The FDA “issued interim guidance on voluntary labeling of milk from untreated cows, concluding that such milk cannot be labeled as ‘BST free’ because BST occurs naturally in milk, but that farmers may label their milk ‘from cows not treated with rbST,’ if the statement is placed in proper context.”³⁰ The FDA suggested that proper context might be derived by “pairing a production claim with the statement that ‘[n]o significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows,’ or ‘by conveying the firm’s reasons (other than safety or quality) for choosing not to use milk from cows treated with rbST.’”³¹

Following the FDA’s guidance, Ohio banned claims like “rBST-free,” and limited labeling for the absence of rBST technology to claims like “this milk is from cows not supplemented with rbST” followed by “The FDA has determined that no significant difference

²⁶ *International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996).

²⁷ *Id.* at 81.

²⁸ *Stauber v. Shalala*, 895 F. Supp. 1178,1188 (W.D. Wis. 1995).

²⁹ *Id.*

³⁰ 59 F.R. 6279-80 (Feb. 10, 1994); *Stauber v. Shalala*, 895 F. Supp. 1178,1188 (W.D. Wis. 1995).

³¹ *International Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 633 (6th Cir. 2010).

has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows.”³²

Dairy producing organizations sued to overturn the restrictions on labeling for the non-use of rbST. Based on the court’s agreement with scientific evidence presented by amici, the court disagreed with the FDA’s finding that no significant difference exists between milk from cows treated with rbST and cows not treated with rbST.³³ It held that therefore “rbST-free” claims were not misleading, and that therefore, Ohio could not ban them.³⁴

Similar suits have occurred in other states, and many people have protested against attempts in other states to prevent dairy farmers from labeling their milk non-rbST.³⁵

2. Genetically Engineered Foods

Genetic engineering involves making small changes to the DNA of a food organism in order to change characteristics of that organism so that it will, for example, grow more quickly. The DNA manipulation resulting from genetic engineering is very similar to what occurs when plants or animals are bred to have certain characteristics.

i. Mandatory labeling

The FDA decided not to require labeling for all genetically engineered foods.³⁶ It decided this for plants in 1992,³⁷ and more recently for animals, in 2009.³⁸ Originally when it

³² *Id.* at 634.

³³ *Id.*

³⁴ *Id.*

³⁵ See, e.g., 93 *Consumer Environmental Groups and Dairies Urge Kansas to Not Ban Milk Hormone Labeling; Recent Similar Attempts to Ban rBGH-Free Labels in Other States have Failed*, Feb. 25, 2008, available at http://www.consumersunion.org/pub/core_food_safety/005456.html.

³⁶ *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance*, (Jan. 2001) available at <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodlabelingnutrition/ucm059098.htm>

³⁷ *Statement of Policy: Foods Derived from New Plant Varieties*, FDA, 57 F.R. 22984 (May 29, 1992), cited in HUTT & MERRILL, *supra* note 14, at 145.

decided this for plants, it explained that it was “not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act.”³⁹

In 2003, the Deputy Commissioner of the FDA, in a statement before congressional subcommittees, explained the types of changes the FDA would consider material, if caused by genetic engineering:

If genetic modifications [change a food’s] nutritional content (for example, more oleic acid, or greater amino acid or lysine content) or requirements for storage, preparation, or cooking, which might impact the food’s safety characteristics or nutritional qualities[or cause it to] contain an allergen not previously found in that food, these would be material changes.⁴⁰

The D.C. Circuit upheld the FDA’s policy of not mandating labeling for genetically engineered food in *Alliance for Bio-Integrity v. Shalala*.⁴¹ A group of “eminent scientists, public interest organizations, and people from diverse faiths who reject genetically altered foods on the basis of religious principle”⁴² had challenged the FDA’s policy not to require labeling.

They claimed that “FDA should have considered the widespread consumer interest in having genetically engineered foods labeled, as well as the special concerns of religious groups and persons with allergies in having these foods labeled.”⁴³ They challenged the FDA's

³⁸ *Genetic Engineering: General Q&A*, FDA, available at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm>. (*I’m not positive if this was the first time they approved it for animals.*)

³⁹ *Bioengineering Draft Guidance*, *supra* note 40.

⁴⁰ Crawford, *supra* note 14.

⁴¹ 116 F. Supp. 2d 166 (D.C. Cir. 2000).

⁴² *Alliance for Bio-Integrity, Purposes and Goals*, available at <http://www.biointegrity.org/>.

⁴³ *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178 (2000).

exclusion of consumer interest from the factors determining whether a change is “material” under 21 U.S.C. 321(n).⁴⁴

Analyzing the FDA’s interpretation under *Chevron*, the court explained that “Congress has not squarely addressed whether materiality pertains only to safety concerns or whether it also includes consumer interest,” and that the agency’s interpretation was reasonable.⁴⁵

The court also questioned whether the FDA would have the power to “require labeling in a situation where the sole justification for such a requirement is consumer demand,” and cited *Stauber*.

The court explained that consumer interest does still play a role in labeling, however.⁴⁶ It stated that, after the FDA has determined that a food has been materially changed, consumer interests are a factor in whether a label is required.⁴⁷ The court quoted language from *Stauber* in explaining this.

The FDA argued that “material change,” under § 321(n), meant “increased” or “unique.” “Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact. Thus, ‘if there is a [material] difference, and consumers would likely want to know about the difference, then labeling is appropriate. If, however, the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different.’”⁴⁸

ii. Voluntary Labeling

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.* at 179.

⁴⁷ *Id.*

⁴⁸ *Id.*

The FDA has developed draft guidance for those who wish voluntarily to label either the presence or absence of bioengineered food in food products.⁴⁹ In it, it discourages the use of terms like “GMO free” and “not genetically modified.”⁵⁰

It explained that these labels are not accurate as stand-alone claims.⁵¹ Since GMO stands for genetically modified organisms, this implies that other food has organisms in it, which is often not the case. Probably no food can claim to be “not genetically modified” because humans have been genetically modifying crops and livestock for centuries.

3. Cloned and other Genetically Engineered Animals

FDA does not require that meat from cloned cattle, swine or goats be labeled as such.⁵² So far this has not been challenged in court. Scientists agree that the meat from cloned animals is no different than the meat from not-cloned animals. The FDA has not required labeling for cloned animals because of this.⁵³

FDA explained that cloning fits into a continuum of assisted reproductive technologies: “Assisted reproductive technologies (ARTs) have been employed extensively in animal agriculture for over a century, and at least one (artificial insemination) has been practiced for several hundred years. These technologies form a continuum that ranges from the fairly minimal assistance provided to animals engaged in natural service through the more recent development of SCNT. ARTs have aided in the genetic improvement of domestic livestock species by the

⁴⁹ *Bioengineering Draft Guidance*, *supra* note 40.

⁵⁰ Crawford, *supra* note 14.

⁵¹ *Bioengineering Draft Guidance*, *supra* note 40.

⁵² See Donna M. Byrne, *Cloned Meat, Voluntary Food Labeling, and Organic Oreos*, 8 PIERCE L. REV. 31 (Dec. 2009); Matthew R. Kain, Comment, *Throw Another Cloned Steak on the Barbie: Examining the FDA's Lack of Authority to Impose Mandatory Labeling Requirements for Cloned Beef*, 8 N.C. J. L. & TECH. 303 (Spring 2007).

⁵³ B. George Walker, *Double Trouble: Competing Federal and State Approaches to Regulating the New Technology of Cloned Animal Foods, and Suggestions for the Future*, 14 J. TECH. L. & POL'Y 29 (2009); Murphy, John F. *Mandatory Labeling of Food Made From Cloned Animals: Grappling with Moral Objections to the Production of Safe Products*, 63 FOOD & DRUG L.J. 131 (2008).

selection and propagation of desirable phenotypes, and accelerating the rate at which those characteristics have been incorporated into national herds.”⁵⁴

A Cloned Food Labeling Act was proposed that required labeling for meat from cloned animals or the “progeny” of cloned animals.⁵⁵ Its proponents argued that the Act would “ensure that the potential human health, animal health, and economic impacts associated with animal cloning that are missing from the FDA’s risk assessment are fully analyzed before any products derived from clones are introduced into the food market.”⁵⁶

Progeny was not defined in the bill,⁵⁷ but it is interesting to consider how many generations the taint of cloning would attach to the meat or other products of cloned animals, assuming that further generations were produced using traditional breeding methods.

4. Farm-raised and Wild-caught Fish and Shellfish

Congress recently mandated labeling for fish, specifically, whether the fish and shellfish were wild-caught or farm-raised.⁵⁸ When the USDA sought comments on the statute’s implementation, one commenter requested that more details be added to the labeling of fish:

for wild fish, the method of harvest (i.e., long-line, gillnet, trawl, purse seine, line and hook); and for farm-raised fish (1) whether it is a genetically engineered,

⁵⁴ *Safety of Food from Animals Clones Final Risk Assessment*, 27 BIOTECH.L.R. 141 (Apr. 2008).

⁵⁵ H.R.992, Title: Cloned Food Labeling Act, Sponsor: Rep DeLauro, Rosa L. [CT-3] (introduced 2/12/2007); S.414 Title: Cloned Food Labeling Act, Sponsor: Sen Mikulski, Barbara A. [MD] (introduced 1/26/2007).

⁵⁶ *Center for Food Safety and Consumers Union Challenge Governor Schwarzenegger’s Veto of Cloned Food Bill on Federal Preemption Grounds*, ConsumersUnion.org(Nov. 14, 2007), available at http://www.consumersunion.org/pub/core_food_safety/005191.html.

⁵⁷ *Text of S. 414 [110th]: Cloned Food Labeling Act*, govtrack.us, available at <http://www.govtrack.us/congress/billtext.xpd?bill=s110-414>.

⁵⁸ 2002 Farm Bill, Pub. L. No. 107-171 § 10816, 116 Stat. 134, 533-35, amending the Agricultural Marketing Act of 1946 (AMS), 7 U.S.C. §§ 1621-1637b (codified at 7 U.S.C. §§ 1638-1638d).

and (2) the feed conversion ratio (quantity of fish feed required for producing the end commodity).⁵⁹

The agency responded by explaining that “[t]he statute only provides the Agency with the authority to require that fish and shellfish carry notification for country of origin and that the covered commodity distinguish between wild fish and farm-raised fish. Therefore, the additional labeling information cannot be required.”⁶⁰

Some claim that the FDA’s requirement for labeling when artificial color is added to farm-raised salmon (to make it appear wild-caught) demonstrates that the FDA has a broader ability to require labeling than it claims to have with genetically modified foods.⁶¹ This argument suggests that consumer interest in knowing about processing, whether fish is farm-raised or wild-caught, played a role in the FDA’s decision to require the labeling, as food color labeling would serve as a proxy for the farm-raised/wild-caught distinction. However, the FDA requires labeling for the salmon because its governing statute mandates labeling when artificial colors are added to food.⁶²

5. Irradiation

Irradiation, or ionizing radiation, uses radiation technology to kill microorganisms in food, similar to heat treatments like pasteurization or canning.⁶³ In 1986, the FDA decided to require labeling for food exposed to certain types of irradiation.⁶⁴ The FDA stated that there

⁵⁹ 74 F.R. 2668, (Jan 15, 2009), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5074925>.

⁶⁰ *Id.*

⁶¹ Douglas A. Kysar, *Preferences for Processes: The Process/product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, fn. 134(2004).

⁶² See 63 F. R. 14814 (Mar. 27, 1998); *In re Farm Raised Salmon Cases*, 175 P.3d 1170 (2008).

⁶³ *Food Irradiation*, CDC, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodirradiation.htm#whatis>.

⁶⁴ David Alan Nauheim, *Food Labeling and the Consumer’s Right to Know: Give the People What They Want*, 4 LIBERTY U. L. REV. 97, 124-125 (2009).

were no safety reasons to label irradiation, but that it did so because otherwise consumers might be deceived into thinking that the food had not been processed.

The FDCA includes ionizing radiation as a food additive and require that food that is irradiated be labeled as irradiated.⁶⁵ However, according to FDA regulations, food that is made of multiple components doesn't have to be so labeled. The FDA has explained that this is because people recognize that the food has been processed.

“FDA concluded that labeling indicating treatment of food with radiation was necessary to prevent misbranding of irradiated foods because irradiation may not visually change the food and in the absence of a label statement, the implied representation to consumers is that the food has not been processed.”⁶⁶ “As part of the FDA Modernization Act of 1997, Congress amended the FDC Act to create §403C, which provides that . . . second-stage products need not be labeled as irradiated; for example, sprouts from irradiated seeds or products incorporating irradiated spices do not need to be labeled as irradiated.”⁶⁷

The FDA's reasoning on these decisions seems inconsistent with other times where the important question has not been whether a food was processed but whether the food was materially changed by that process.

Frank Degnan, the author of an excellent article on this subject entitled “The Food Label and the Right-to-Know,” wrote in 1997 that irradiation was the only case in which the FDA “relied on sections 403(a) and 201(n) to require the disclosure on the food label of a processing technique applied to food.”⁶⁸ He explained that “[a]lthough the comments FDA received

⁶⁵ *Irradiated Food and Packaging Overview*, FDA, available at <http://www.fda.gov/Food/FoodIngredientsPackaging/IrradiatedFoodPackaging/default.htm> (“The 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act) where Congress explicitly defined a source of radiation as a food additive (Section 201(s) of the FD&C Act).”),

⁶⁶ 72 FR 16291.

⁶⁷ Jonathan E. Prejean, *Food Irradiation: Why Aren't We Using It?* Electronic Book (2001).

⁶⁸ Degnan, *supra* note 17, at 52.

regarding its initiative expressed concern about the safety of irradiation, the requirement was not based on fears about safety. Instead, the agency concluded that irradiation could cause changes in the flavor or shelf-life of the finished foods and that these changes could be significant and material in light of the consumer's perception of the food as unprocessed.”⁶⁹

Some people, however, claim that the FDA mandated labeling for irradiation “based on consumer interest alone.”⁷⁰

“In May 13, 2002, the President signed into law the FSRIA, which contains a provision directing the FDA to revise the current regulation governing the labeling of foods that have been treated by irradiation.”⁷¹ In response to that law, in 2007 the FDA put forth a proposed rule.⁷² The agency proposed not requiring labeling irradiated food except for in circumstances where there actually were material differences in the food resulting from irradiation.⁷³

For example, the agency stated that irradiated bananas would need to be labeled as irradiated, because irradiating bananas slows their ripening process.⁷⁴ The agency explained that this would be a material change because otherwise banana bread makers would be deceived, because they purchase bananas to make banana bread expecting them to turn brown more quickly than irradiated bananas would turn brown.⁷⁵ This suggests that no irradiation that lengthens a food's shelf life would be considered immaterial under the proposed regulations.

6. Organically Produced Foods

⁶⁹ Degnan, *supra* note 17, at 52-53.

⁷⁰ Nauheim, *supra* note 68, at 124-125.

⁷¹ 72 F. R. 64, 16297 (Apr. 4, 2007).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

People began marketing food as “organic” in the 1950s.⁷⁶ In 1990, Congress set standards for organic foods in the Organic Foods Production Act.⁷⁷ “USDA defines organic agriculture as ‘ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity based on minimal use of off-farm inputs and on management practices that restore, maintain, and enhance ecological harmony.’”⁷⁸

Organic labeling is voluntary.⁷⁹ Organic farms can use only certain pesticides.⁸⁰ Farmers may not use antibiotics on organic livestock,⁸¹ and the livestock must be raised under certain conditions⁸² The regulations for organic milk are complicated, but basically the cows must have been fed mostly organic feed for at least one year prior to the milk being produced. Organic foods cannot be irradiated⁸³ or produced “using biotechnology methods.”⁸⁴ Originally the organic food regulations proposed including genetically engineered food, but USDA changed its mind after a large public outcry.⁸⁵

The USDA originally proposed allowing organic farmers to use “genetic engineering, irradiation, and sewage sludge in organic production,” but these options were dropped after objections from the public.⁸⁶

Organic food costs more to produce, but some consumers are willing to pay a premium for food grown organically.⁸⁷ “Second, somehow ‘organic’ quality is in competition in the

⁷⁶ Cathy Greene, *Organic Labeling*, 26, in Elise Golan, et al., *Economics of Food Labeling*, AGRICULTURAL ECONOMIC REPORT NO. 793, (Jan. 2001), available at <http://www.ers.usda.gov/publications/aer793/AER793.PDF>.

⁷⁷ NEAL D. FORTIN, *FOOD REGULATION: LAW, SCIENCE, AND PRACTICE*, 92 (2009).

⁷⁸ FORTIN, *supra* note 78, at 92.

⁷⁹ A. Christine Green, *Commentary: The Cost of Low-Price Organics: How Corporate Organics Have Weakened Organic Food Production Standards*, 59 ALA. L. REV. 799 (2008).

⁸⁰ *USDA Response to NOSB Feedback on Issue Statements: Fishmeal, Inerts, Antibiotics, and Scope of Authority*, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3099366>.

⁸¹ *Id.*

⁸² *Id.*

⁸³ Organic Food Program, 65 F. R. 80,548 (2000) (7 C.F.R. 205).

⁸⁴ *Bioengineering Draft Guidance*, *supra* note 40.

⁸⁵ Green, *supra* n. 83.

⁸⁶ Greene, *supra* note 80, at 27-28; *see also*, Green, *supra* n. 83.

public's conception with what is referred to as 'healthful' and hygienic food . . . While organic standards may not claim to be more healthful, they do put a negative value on the use of chemicals, irradiation and GMOs. Hence they play a role in the deconstruction of a previously unquestioned public credence and they displace public debate.”⁸⁸

7. Water Fluoridation

Adding fluoride to water helps reduce tooth decay.⁸⁹ Water fluoridation in the United States began in 1945.⁹⁰ Now more than 72% of the United States population receives fluoridated water.⁹¹ “The CDC has recognized has recognized water fluoridation as one of 10 great public health achievements of the 20th century.”⁹²

Water from faucets does not come labeled, although now consumers can look online to see whether their water is fluoridated.⁹³ “The FDA does not require bottled water manufacturers to list the fluoride content on the label, but it does require that fluoride additives be listed.”⁹⁴ If water is labeled “de-ionized, purified, demineralized, or distilled,” it will be low-fluoride unless fluoride is labeled as an additive.⁹⁵ The FDA recommends that consumers concerned about the level of fluoride in bottled water “[c]ontact the bottled water’s manufacturer to ask about the

⁸⁷ Greene, *supra* note 80, at 26.

⁸⁸ Gilles Allaire, *Quality in economics: a cognitive perspective*, 75 in *QUALITIES OF FOOD* (MARK HARVEY, ET AL., EDS.) (2004).

⁸⁹ *Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States. CDC MMWR, Recommendations and Reports*, 1-42, 50 (RR14) (Aug. 17, 2001).

⁹⁰ *CDC Honors 65 Years of Community Water Fluoridation*, CDC, available at http://www.cdc.gov/fluoridation/65_years.htm (On January 25, 1945, the city of Grand Rapids, Michigan was the first city to fluoridate its water. In 1951, after analyzing the results of fluoridation on tooth decay, the National Academy of Sciences' National Research Council declared it safe, effective, and beneficial.).

⁹¹ *Id.*

⁹² *Community Water Fluoridation, Overview*, CDC available at <http://www.cdc.gov/fluoridation/index.htm>, citing *Ten Great Public Health Achievements -- United States, 1900-1999*, (Apr. 2, 1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm>.

⁹³ *My Water's Fluoride*, CDC, available at <http://apps.nccd.cdc.gov/MWF/Index.asp>.

⁹⁴ *Bottled Water and Fluoride*, available at http://www.cdc.gov/fluoridation/fact_sheets/bottled_water.htm.

⁹⁵ *Id.*

fluoride content of a particular brand.”⁹⁶ In 2006 the FDA recently approved the use of the statement “Drinking fluoridated water may reduce the risk of tooth decay,” if the bottled water contains a certain amount of fluoride.”⁹⁷

Some argue that community water systems should not be fluoridated.⁹⁸ One article argues that “[s]ilicofluorides, widely used in water fluoridation, are unlicensed medicinal substances, administered to large populations without informed consent or supervision by a qualified medical practitioner.”⁹⁹

8. Dolphin-Safe Tuna.

Tuna fishers used to kill dolphins with certain methods of tuna fishing.¹⁰⁰ After consumers became aware of this, in 1990, tuna sellers voluntarily began labeling their tuna “dolphin-safe.”¹⁰¹ Later that year, Congress passed the Dolphin Protection Consumer Information Act, which regulated labeling of dolphin-safe characteristics. A recent report by the FDA explains that this was done “to prevent fraud,” because people were concerned that unless the dolphin-safe label was regulated, “firms that used technology that was harmful to dolphins might be labeling [their tuna] erroneously.”

9. Iodized Salt

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ See, e.g., *Murky Waters Lurk at Home*, NOFLUORIDE.COM, CITIZENS FOR SAFE DRINKING WATER available at http://www.nofluoride.com/betternutrition_article.cfm (citing the former chief chemist at the National Cancer Institute as stating that “Fluoride causes more cancer, and causes it faster, than any other chemical,” listing fluoride-free bottled water companies); Paul Connett, *The Absurdities of Water Fluoridation*, RED FLAGS WEEKLY, (Nov. 28, 2002), available at <http://www.fluoridealert.org/absurdity.htm>.

⁹⁹ D.W. Cross, *Fluoridation: a violation of medical ethics and human rights*, 9 INT. J. OCCUP. ENVIRON HEALTH, 1, 24-29 (Jan.-Mar. 2003).

¹⁰⁰ Lorraine Mitchell, *Dolphin-Safe Tuna Labeling*, 22-23, in Elise Golan, et al., *Economics of Food Labeling*, AGRICULTURAL ECONOMIC REPORT NO. 793, (Jan. 2001), available at <http://www.ers.usda.gov/publications/aer793/AER793.PDF>.

¹⁰¹ *Id.*

Iodine was added to salt beginning in 1924 to reduce iodine deficiency.¹⁰² “Iodine deficiency disorders include mental retardation, hypothyroidism, goiter, cretinism, and varying degrees of other growth and developmental abnormalities. Iodine deficiency is the most preventable cause of mental retardation in the world.”¹⁰³ Few people challenge the safety and efficacy of adding of iodine to salt; those who do seem to be doing so as an advertisement for iodine supplements or alternative salts.¹⁰⁴

Iodized food is labeled. This is important because some people, including those with Graves disease, need to avoid iodine in their diets.¹⁰⁵

10. Food Produced Abroad¹⁰⁶

“The 2002 and 2008 Farm Bills amended the Agricultural Marketing Act of 1946 to require retailers to notify their customers of the country of origin of beef (including veal), lamb, pork, chicken, goat, wild and farm-raised fish and shellfish, perishable agricultural commodities, peanuts, pecans, ginseng, and macadamia nuts.”¹⁰⁷

Meats covered by the bills must “take into account all the production steps (born, raised, and slaughtered) for animals that the meat is derived from.”¹⁰⁸ Only animals born, raised, and

¹⁰² *The History of Morton Salt*, available at http://www.mortonsalt.com/heritage/history_morton-salt.html.

¹⁰³ *Trace Elements: Iodine*, CDC, available at http://www.cdc.gov/nutritionreport/pdf/nr_ch4a.pdf.

¹⁰⁴ Edward Group, *Iodine in Salt: Why Is It Added?* GLOBAL HEALING CENTER, Mar. 29, 2011, available at <http://www.globalhealingcenter.com/natural-health/iodine-in-salt/> (“‘Iodized Salt’ is not a healthy naturally occurring rock, crystal or sea salt.”); Pat Thomas, *What type of salt is best?* THE ECOLOGIST, Mar. 1, 2009 http://www.theecologist.org/green_green_living/health_and_beauty/270993/what_type_of_salt_is_best.html (“The addition of iodine to table salt is a real problem and makes the ‘simple’ table salt so many of us rely on little more than a poison.”).

¹⁰⁵ *Foods with Iodine that People with Graves Disease Should Avoid*, LiveStrong available at <http://www.livestrong.com/article/333891-foods-with-iodine-that-people-with-graves-disease-should-avoid/>.

¹⁰⁶ Country of origin may not exactly count as a method of production, but I include this because it seems important to developing any overall thesis about how food labeling decisions are or should be made.

¹⁰⁷ *Country of Origin Labeling: Frequently Asked Questions*, (Sept. 26, 2008), available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5071922>.

¹⁰⁸ *Consumer Questions and Answers on Country of Origin Labeling*, USDA, available at <http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=COOLConsumerInformation&rightNav1=COOLConsumerInformation&topNav=&leftNav=CommodityAreas&page=COOLConsumerQA&resultType=&acct=AMSPW>.

slaughtered exclusively in the United States “may be labeled with ‘Product of US.’”¹⁰⁹

Otherwise “all possible combinations of countries must be accounted for when the meat is processed.”¹¹⁰ For example, if cows born in Mexico and others born in Canada are commingled through the raising or slaughter process . . . the resulting product would be labeled as “Product of US, Canada and Mexico.”¹¹¹

11. Fruit Juice Pasteurization¹¹²

Pasteurization heats liquids to kill most of the microorganisms in the liquid. After an incident in 1996 where sixty-five people became sick after drinking unpasteurized apple juice, including one 16-month old girl who died, “there was pressure from public health proponents for pasteurization of all juices.”¹¹³

“In response, the Food and Drug Administration [required] all fresh juices, both fruit and vegetable, to be processed to remove harmful bacteria -- through pasteurization or other means.”¹¹⁴ In addition, since 1999 the FDA has required unpasteurized juice or cider to carry a warning label.¹¹⁵ The label reads “**WARNING:** This product has not been pasteurized and therefore may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.”¹¹⁶

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² Raw, unpasteurized milk is a growing issue as more and more people advocate for it. However, it is outside the scope of this paper because milk pasteurization laws vary by states. That’s also true for rBST, but somehow rBST seems to fit in my paper more than raw milk does.

¹¹³ Marian Burros, *Eating Well; is it Pasteurized? Juice Labels Will Tell*, (July 1, 1998), available at <http://www.nytimes.com/1998/07/01/dining/eating-well-is-it-pasteurized-juice-labels-will-tell.html?pagewanted=1>.

¹¹⁴ *Id.*; see also, William M. London, *What Comes Naturally: Contaminated Apple Juice and Opposition to Pasteurization*, 8 PRIORITIES 4, (Oct. 1, 1996) available at http://www.acsh.org/healthissues/newsID.725/healthissue_detail.asp.

¹¹⁵ *Talking about Juice Safety: What You Need to Know*, FDA, available at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm110526.htm>; *Food Labeling: Warning and Notice Statement; Labeling of Juice Products*, 63 FR 37029, July 8, 1998, available at <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/JuiceHACCP/ucm082009.htm>.

¹¹⁶ Juice Safety, *supra* note 119; 21 CFR 101.17(g)(2).

The FDA does not require warning labels for “juice or cider that is fresh-squeezed and sold by the glass, such as at apple orchards, at farm markets, at roadside stands, or in some juice bars.”¹¹⁷

12. Grass Fed Animals

As one of its voluntary U.S. Standards for Livestock and Meat Marketing Claims, the USDA in 2007 set a standard for the use of claims that meat comes from cows that were grass fed.¹¹⁸

The agency explained that some people wanted the grass fed label to be limited to animals that were not fed genetically modified plants and forage.¹¹⁹ The agency explained that “the requirement prohibiting the use of genetically engineered plants is not included due to the lack of research showing effects on animals consuming genetically engineered plants.”¹²⁰

13. Caffeinated Products

Caffeine occurs naturally in some products, and it is added to others. Since at least 1997, people have been encouraging the FDA to mandate labeling for caffeine content in foods.¹²¹ The FDA explains that it does not require labeling for caffeine because caffeine is not a nutrient.¹²² “The Nutrition Facts Panel on food labels is required to include recommended dietary information for nutrients.”¹²³

¹¹⁷ Juice Safety, *supra* note 119; 21 CFR 101.17(g)(3).

¹¹⁸ *United States Standards for Livestock and Meat Marketing Claims, Grass (Forage) Fed Claim for Ruminant Livestock and the Meat Products Derived From Such Livestock*, Agricultural Marketing Services, USDA, 72 F.R. 199, 58631 (Oct. 16, 2007), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5063842>.

¹¹⁹ *Id.* at 58636.

¹²⁰ *Id.*

¹²¹ *Label Caffeine Content of Foods, Scientists Tell FDA*, CSPI (July 31, 1997), available at <http://www.cspinet.org/new/caffeine.htm>.

¹²² *Why isn't the amount of caffeine a product contains required on a food label?* FDA Basics Questions, available at <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194317.htm>.

¹²³ *Why isn't the amount of caffeine a product contains required on a food label?* FDA Basics Questions, available at <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194317.htm>.

“Because caffeine is an added ingredient in soft drinks and caffeinated water, caffeine must be included in ingredient lists. But the labels do not have to disclose how much caffeine those foods contain. Neither the presence nor amount of caffeine is indicated on most labels of tea, coffee, and foods made with those beverages, such as ice cream and yogurt.”¹²⁴

Some manufactures have begun to voluntarily label their products’ caffeine content. “In 2007, Coca-Cola and Pepsi began listing caffeine content on beverage labels, citing a desire to give consumers more information. Consumers can now see for themselves that an 8-ounce serving of Coca-Cola contains 23 milligrams of caffeine and that the same amount of regular Pepsi contains 25.”¹²⁵

C. Labeling Technologies and Production Methods in the European Union

1. Technologies not used or approved

The European Union does not use some of the types of technologies that the United States does. A number of the countries in the European Union have stopped fluoridating their water.¹²⁶ In the European Union, when fluoride is removed from spring and natural mineral waters, “[t]he use of a fluoride removal treatment should be indicated on the label of treated water.”¹²⁷

In 1981 (with Directive 81/602/EEC), the EU prohibited the use of “substances having a hormonal action for growth promotion in farm animals.”¹²⁸ “The United States and Canada contested the prohibition of the use of hormones as growth promoters in food producing animals,

¹²⁴ *Label Caffeine Content*, *supra* note 125.

¹²⁵ Elena Conis, *Labeling standards for caffeine*, LA TIMES, Dec. 28, 2009, available at <http://articles.latimes.com/2009/dec/28/health/la-he-nutrition28-2009dec28>.

¹²⁶ *Letter to the Editor: Fluoridation in Europe* 31 FLUORIDE 3, 171-174 (1998), available at <http://www.fluoride-journal.com/98-31-3/313-171.htm> (those countries include Germany, Sweden, Czechoslovakia, Soviet Union, and Finland).

¹²⁷ E.U. Commission Reg. No. 115/2010 (Feb. 2010) available at <http://fluoridealert.org/re/eu.mineral.and.spring.water.2010.pdf> (laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters).

¹²⁸ http://ec.europa.eu/food/food/chemicalsafety/contaminants/hormones/index_en.htm

and in 1997 a panel of the World Trade Organisation (WTO) ruled that the EU measure was not in line with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). The EU appealed against this ruling and, in 1998, the WTO Appellate Body reversed most of the findings of the panel. The WTO Appellate Body only upheld the finding that prohibition of imports of meat from hormone-treated animals to the EU did not comply with the requirement that such a measure should be based on a relevant assessment of the risks to human health.”¹²⁹

2. Mandatory Labeling

When the European Union does approve food technologies, it is more likely than the United States to require labeling. For example, in the EU, labeling of genetically modified food has been mandatory since 1997.¹³⁰

Irradiated food has to be labeled.¹³¹ “Irradiated” or “treated with ionising radiation” has to be on the label.¹³² Even if an irradiated product is used as an ingredient, “the same words shall accompany its designation in the list of ingredients.”¹³³ Originally, however, if irradiated products constituted less than 25% of a finished product, they did not have to be labeled.¹³⁴

So far, the list of products approved for irradiation within the whole EU contains only a single food category: “dried aromatic herbs, spices and vegetable seasonings.”¹³⁵ Although, “[i]n 1986, 1992 and 1998 [there were] favourable opinions on irradiation of fruit, vegetables, cereals, starchy tubers, spices and condiments, fish, shellfish, fresh meats, poultry, camembert

¹²⁹ http://ec.europa.eu/food/food/chemicalsafety/contaminants/hormones/aspects_en.htm

¹³⁰ *GM Food and Feed – Labeling*, FOOD SAFETY – FROM THE FARM TO THE FORK, available at http://ec.europa.eu/food/food/biotechnology/gmfood/labelling_en.htm.

¹³¹ *Food Irradiation – Community Legislation*, in FROM THE FARM TO THE FORK, *supra* note 33.

¹³² Article 5(3) of Directive 79/112/EEC.

¹³³ Article 6 of Directive 79/112/EEC.

¹³⁴ Article 5(3) of Directive 79/112/EEC.

¹³⁵ FROM THE FARM TO THE FORK, *supra* note 33.

from raw milk, frog legs, gum arabic, casein/caseinates, egg white, cereal flakes, rice flour, and blood products.”¹³⁶

Beef labels have included the place of fattening, slaughtering, and cutting, and precise information about where the animal was born and reared, since 2002.¹³⁷

Although not all caffeine in beverages arises through technology, some does, and some people in the United States have been advocating for caffeine labeling. With exceptions for coffee and tea, beverages containing more than 150 mg/l of caffeine must be labeled as having “high caffeine content,” since 2002 in the EU.¹³⁸

D. Potential Food Labeling Rubrics

The purpose of researching and listing the various food labeling requirements was to see if a closer look at how food labeling decisions have been made would reveal some sort of consistency that was not immediately apparent upon comparing the various decisions. The following represent two different schemas for making labeling decisions.

1. Distance from production method’s application to consumption

Perhaps the proximity of the application of the technology to the consumption of the product should matter. This may be a way to understand why, for example, irradiation requires labeling but genetic engineering and cloning technologies do not.

Cloning technology and genetic engineering both affect organisms before they even come into being, or as they come into being, and labeling them would require tracing the organism as it progressed from seed to fruit, or zygote to adult, etc. On the other hand, labeling is required for irradiation when it occurs relatively immediately before consumption.

¹³⁶ FROM THE FARM TO THE FORK, *supra* note 33.

¹³⁷ *Food Labeling – Labeling of Beef*, in FROM THE FARM TO THE FORK, *supra* note 33.

¹³⁸ COMMISSION DIRECTIVE 2002/67/EC; Official Journal of the European Communities of 18 July 2002 on the labeling of foodstuffs containing quinine, and of foodstuffs containing caffeine.

The FDA's requirements for irradiation are consistent with this schema in that, for example, vegetables grown from irradiated seeds does not have to be labeled, but if the vegetables themselves are irradiated, labeling is required.

However, exceptions to this rule are easy. Although not discussed above, food treated with chemicals¹³⁹ or covered with wax, almost immediately before consumption, do not require labeling. If this rubric were applied, then these foods would need to be labeled as waxed or fumigated, etc. (Although, perhaps they ought to be. Evidence suggests fruits ripened while being transported, by ethylene, have fewer nutrients than those that ripen on the tree or vine, and waxy fruit can be deceptive, seeming firm on the outside but rotten on the inside.)

Further, this observation may not be particularly useful merely because there may not be a logical reason why the nearness or farness from the point of consumption that food processing happens during a food organisms' life cycle should determine whether or not the technology should be labeled, except for concerns the cost or feasibility about tracking food through generations. Also, this rubric really only is helpful for technologies or production methods that have a discrete time at which they are applied to a food product: farm-raised fish is likely farm-raised from conception to immediately prior to consumption.

2. Food technologies occurring along a continuum

At least twice now the FDA has, in explaining why it did not require labeling, relied heavily on fact that the technology was merely the recent step in a long tradition of technology. It explained that genetically modified foods were the most recent step in a long chain of genetic

¹³⁹ Spices fumigated to reduce pathogens and fruits and vegetables picked before ripe but treated with ethylene along the journey are examples of this.

modifications,¹⁴⁰ and that cloning was the most recent step in a long chain of assisted reproduction technologies.¹⁴¹

In 1992, the FDA put out a Statement of Policy on plant foods developed using genetic engineering.”¹⁴² In the statement, the FDA compared genetic engineering to other traditional breeding methods of producing new plant varieties “such as hybridization, chemical and radiation-induced mutagenesis, protoplast fusion, embryo rescue, somaclonal variation, or any other method) and explained that genetic engineering is just another step on this continuum.¹⁴³ Since none of these other techniques were “considered to be material information within the meaning of section 201(n) of the act” and thus not required to bear special labeling, the FDA was not going to require genetically engineered foods to be labeled either.”¹⁴⁴

FDA explained how cloning fits into a continuum of assisted reproductive technologies: “Assisted reproductive technologies (ARTs) have been employed extensively in animal agriculture for over a century, and at least one (artificial insemination) has been practiced for several hundred years. These technologies form a continuum that ranges from the fairly minimal assistance provided to animals engaged in natural service through the more recent development of SCNT. ARTs have aided in the genetic improvement of domestic livestock species by the selection and propagation of desirable phenotypes, and accelerating the rate at which those characteristics have been incorporated into national herds.”¹⁴⁵

i. Irradiation is one of many types of radiation used to process foods

¹⁴⁰ *Genetically Engineered Foods*, Statement of James H. Maryanski, Biotech Coordinator, CFSAN (Oct. 19, 1999), available at

<http://www.fda.gov/newsevents/testimony/ucml15032.htm>.

¹⁴¹ Pete Kennedy, *Food Safety- Can FDA Be Trusted?* Farm-to-Consumer Legal Defense Fund, available at http://www.ftcldf.org/news/news-29jan2010-food_safety.html.

¹⁴² *Statement of Policy*, supra n. 41.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Animal Clones*, supra note 58.

This also holds true for irradiation. When people refer to irradiation today, they are referring to irradiation produced by ionizing radiation, as opposed to other types of radiation. Ionizing energy radiation falls along a spectrum of radiation, nearly all other types of which have been used safely and effectively for a variety of food processing purposes. (I believe only ionizing radiation is required to be labeled.)

While scientists can draw a line along the electromagnetic spectrum between ionizing and non-ionizing radiation, the scientific difference does not indicate a reason why ionizing radiation should be labeled. Ionizing radiation differs from non-ionizing radiation in that “[i]onizing radiation “is radiation with enough energy so that during an interaction with an atom, it can remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionized.”¹⁴⁶ Examples of ionizing radiation include alpha and beta particles, neutrons, and gamma and x-rays.¹⁴⁷

Non-ionizing radiation refers to radiation in the electromagnetic spectrum which does not have enough energy to cause an atom to become ionized.¹⁴⁸ “It includes electric and magnetic fields, radio waves, microwaves, infrared, ultraviolet, and visible radiation.”¹⁴⁹

The electromagnetic spectrum ranges from radio waves through gamma rays.¹⁵⁰ People in the United States have grown accustomed to treating their food with microwave energy, and people generally accept its safety.¹⁵¹ Visible and infrared radiation can also be used to cook food.¹⁵²

¹⁴⁶ *What is ionizing radiation?* WHO, available at http://www.who.int/ionizing_radiation/about/what_is_ir/en/index.html.

¹⁴⁷ *Id.*

¹⁴⁸ *Radiation, Non-ionizing*, WHO, available at http://www.who.int/topics/radiation_non_ionizing/en/.

¹⁴⁹ *Id.*

¹⁵⁰ *Electromagnetic Spectrum*, available at http://imagine.gsfc.nasa.gov/docs/science/know_11/emspectrum.html.

¹⁵¹ Thomas J. Hoban, *Why Doesn't The World Want Our GMO Grains? Like the microwave oven or pasteurization, acceptance takes time*, STRATEGIC AGRIBUSINESS REV. 5 (Jan. 2004) available at http://www4.ncsu.edu/~hobantj/whats_new/articles/why_doesnt_the_world_want_gmos.pdf. Some people in

Food technologies have long included exposing foods to ultraviolet radiation.¹⁵³ When people dry food in the sun, in addition making the food inhospitable to microorganism growth by reducing its water content, the ultraviolet radiation that occurs in sunlight kills microorganisms by altering their DNA so that they cannot reproduce effectively. In addition to natural exposure to sunlight, food producers in 1944 investigated the use of ultraviolet radiation to increase the vitamin D content in margarine, to make it more consistent with that of butter.¹⁵⁴ Research was done on using ultraviolet radiation to improve vitamin D content in milk, and although researchers found that over-radiating milk produced bad flavors, for at least a while some milk producers irradiated their milk to increase its vitamin D content, in order to reduce rickets.¹⁵⁵

Today the vitamin D that is added to foods fortified with vitamin D typically is created by exposing certain compounds, for example, an extract from yeast, to ultraviolet radiation.¹⁵⁶ However, at least in some foods, for example, certain mushrooms, vitamin D content is increased by direct exposure of the food to ultraviolet radiation.¹⁵⁷

In the 1950s, some orange juice producers were irradiating fresh orange juice with ultraviolet radiation in order to inactivate “certain enzymes in the juice that cause a rapid deterioration in flavor.”¹⁵⁸ This enabled the juice to have a shelf life up to three weeks, if

Switzerland apparently still question the safety microwaves, *see, e.g.,* A. Kamperman Sanders, *Unfair Competition Law and the European Court of Human Rights the Case of Hertel v. Switzerland and Beyond*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 305, 309 (1999) (discussing 1998 case in which researchers were arguing that microwaves cause cancer and should be banned).

¹⁵² See, e.g., *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 854 (Fed. Cir. 1999).

¹⁵³ *Vitamin Technologists v. Wisconsin Alumni Research Found.*, 146 F.2d 941 (9th Cir. 1944).

¹⁵⁴ *Id.*

¹⁵⁵ *Hanovia Chem. & Mfg. Co. v. David Buttrick Co.*, 39 F. Supp. 646, 651 (D. Mass. 1941) *aff'd*, 127 F.2d 888 (1st Cir. 1942); *R. U. V. Eng'g Corp. v. Borden Co.*, 67 F. Supp. 587, 590 (S.D.N.Y. 1946) *aff'd sub nom. R.U.V. Eng'g Corp. v. Borden Co.*, 170 F.2d 688 (2d Cir. 1948).

¹⁵⁶ *Dietary Supplement Fact Sheet: Vitamin D*, OFFICE OF DIETARY SUPPLEMENTS, NIH, available at <http://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/>. For early forms of this technology, see *In re Tisdall*, 87 F.2d 505, 507 (C.C.P.A. 1937) (patent for irradiating certain ingredients of bread); *In re Spohn*, 77 F.2d 768, 768 (C.C.P.A. 1935) (patent for adding irradiated yeast to cereal).

¹⁵⁷ *Dietary Supplement Fact Sheet: Vitamin D*, *supra* note 159.

¹⁵⁸ *Florida Citrus Comm'n v. Golden Gift, Inc.*, 91 So. 2d 657, 658 (Fla. 1956).

refrigerated.¹⁵⁹ Recent research suggests that ultraviolet radiation is an effective way to reduce microorganisms in fruit juice, without changing the juice's color or taste.¹⁶⁰ In fact, ultraviolet radiation can decompose some toxins not affected by heat processing.¹⁶¹

In a 2008 case, a prisoner complained that x-raying his food violated the fourth amendment. After a brief description of the various organizations that have endorsed the safety of irradiated food, and without distinguishing between the various types of irradiation and whether those safety endorsements were for x-ray radiation specifically, the court held that “it is not plausible to think that Plaintiff could establish that x-raying his meals contaminates his food or otherwise exposes him to any unreasonable health risk.”¹⁶²

The Army began investigating the use of ionizing radiation for food preservation in 1954.¹⁶³ By 1970 there was a suit about a patent for sterilizing foods by irradiating them with “high energy electrons.”¹⁶⁴

In addition to falling among the electromagnetic spectrum, irradiation also is included in the “alternative non-thermal sterilization technologies, such as ionizing radiation, chemical gas treatments, high hydrostatic pressure, pulsed electric fields and radio frequency waves.”¹⁶⁵ Of these other sterilization technologies, I have not heard of any labeling requirements.

E. Labeling Based on Consumer Interest

¹⁵⁹ *Id.*

¹⁶⁰ Maricel Keyser, et al., *Ultraviolet radiation as a non-thermal treatment for the inactivation of microorganisms in fruit juice*, 9 INNOVATIVE FOOD SCI. & EMERGING TECH. 3, 348-354 (July 2008).

¹⁶¹ Víctor Falguera, et al., *Ultraviolet processing of liquid food: A review: Part 2: Effects on microorganisms and on food components and properties*, FOOD RESEARCH INT'L, forthcoming publication, available online Mar. 17, 2011, see doi:10.1016/j.foodres.2011.03.025.

¹⁶² *Hale v. Ashcroft*, CIV.06CV00541REBKLM, 2008 WL 4426125 (D. Colo. Sept. 24, 2008), quoting *Hale v. Ashcroft*, 2007 WL 2350150, *5 (D.Colo.2007).

¹⁶³ *Hasselstrom v. McKusick*, 324 F.2d 1013, 1014 (C.C.P.A. 1963).

¹⁶⁴ *High Voltage Eng'g Corp. v. Boise Cascade Corp.*, 310 F. Supp. 395, 396 (D. Idaho 1970)

¹⁶⁵ ABE 6933 Food and Bioprocess Sterilization Technology, Univ. of Florida, course listing, available at <http://www.abe.ufl.edu/academics/course-listings/graduate/ABE6933.shtml> (See, *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 773 (D. Md. 2002) *aff'd*, 78 F. App'x “the potential for adverse health effects from exposure to radiofrequency radiation has been the subject of scientific discussion for many years.”).

The FDA has upset many people by resisting requests for mandatory labels on food processed in novel ways. Many people in the United States, including a few Congresspersons,¹⁶⁶ scholars,¹⁶⁷ consumer groups,¹⁶⁸ and bloggers,¹⁶⁹ are advocating for a consumer “right to know” regarding how food is processed.

The United States is not alone in having citizens seeking more information about their food. “[C]onsumer organizations in many countries, and some international consumer unions,

¹⁶⁶ See, e.g., H.R.6325 “Consumer Right To Know Food Labeling Act of 2010” sponsored by Representative Rosa DeLauro, <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:h6325>; H.R.992:Cloned Food Labeling Act, Sponsor: Rep DeLauro, Rosa L. [CT-3] (introduced 2/12/2007); S.414: Cloned Food Labeling Act, Sponsor: Sen Mikulski, Barbara A. [MD] (introduced 1/26/2007) (A bill “To amend the Federal Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act to require that food that contains product from a cloned animal be labeled accordingly”); CRS Report for Congress: R.S.20507: Labeling of Genetically Modified Foods (“On November 16, 1999, Representative Dennis Kucinich introduced H.R. 3377, Genetically Engineered Food Right to Know Act, which would require mandatory labeling for all foods containing at least 0.1% ingredients of genetically modified organisms (GMOs).”) <http://digital.library.unt.edu/ark:/67531/metacrs1226/m1/>, & CRS Report for Congress: RS20507: Labeling of Genetically Modified Foods (“On February 22, 2000, Senator Barbara Boxer introduced S. 2080, Genetically Engineered Food Right-to-Know Act, which would require mandatory labeling for all bioengineered foods.”)

¹⁶⁷ See, e.g., Nauheim, *supra* note 68, at 124-125; Christina Cusimano, Comment, *RBST, It Does a Body Good?: RBST Labeling and the Federal Denial of Consumers’ Right to Know*, 48 SANTA CLARA L. REV. 1095 (2008); Emily Robertson, Note, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. OF SCI. & TECH. L. 156 (Winter 2003); Kelly A. Leggio, Comment, *Limitations on the Consumer’s Right to Know: Settling the Debate over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893 (2001); Sarah L. Kirby, *Genetically Modified Foods: More Reasons to Label Than Not*, 6 DRAKE J. AGRIC. L. 351 (2001); Alicia T. Simpson, Note, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?* *Alliance for Bio-Integrity v. Shalala, et al.*, 116 F. Supp. 2D 166 (2000), 19 TEMP. ENVTL. L. & TECH. J. 225 (2001) (arguing that consumer concerns can authorize the FDA to mandate labeling); *but see* Murphy, *supra* note 57 (does a great job addressing the complexities of this issue); Karen A. Goldman, Symposium Articles & Note, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT’L ENVTL. L. REV. 717 (2000); J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105 (2000) (argues against “right to know” in context of genetically modified foods).

¹⁶⁸ *FDA Should Require the Labeling of Genetically Engineered Salmon; Consumers Union’s Senior Scientist to Appear at Veterinary Medicine Advisory Committee Meeting Today and Tomorrow; CU Poll: 95 Percent Want GE Animals Labeled*, (Sept. 20, 2010) available at http://www.consumersunion.org/pub/core_food_safety/016902.html.

¹⁶⁹ See, e.g., Sarah Parsons, *Rally for the Right to Know About GMOs in Your Food*, (Mar. 22, 2011) available at <http://news.change.org/stories/rally-for-the-right-to-know-about-gmos-in-your-food>; *Do We Have a Right To Know If Our Food Has Been Genetically Modified?* WASHINGTON’S BLOG, (Oct. 4, 2010) available at <http://www.washingtonsblog.com/2010/10/do-we-have-right-to-know-if-our-food.html/>; Timi Gustafson, *The Right to Know What’s in Your Food*, (Mar. 29, 2010) available at <http://blogs.pnwlocalnews.com/timigustafson/food/214>.

argue that consumers have a right to get information about products offered on the market that is relevant to their values and preferences.”¹⁷⁰

Some argue that restrictions on food labeling obstruct natural market competition. If someone puts out a superior product, they should be able to indicate this to consumers on their labels. Otherwise, consumers may not know about the product’s superiority, and therefore may not be able to vote with their wallets that they prefer this superior product.¹⁷¹

One scholar argues that “even when consumer process preferences do reflect scientifically unfounded fears, the rejection of ‘mere consumer concern’ as a legitimate state interest overlooks both the potentially significant welfare effects of fear itself, and the more abstract notion that, as Martha Nussbaum observes, ‘there is a distinctive human good expressed in the freedom we give our fellow citizens to make choices that we ourselves may hold to be profoundly wrong.’”¹⁷²

Some people have argued that the FDA has the authority under the FDCA to regulate food based on consumer interest, and that it should do so. One argument is that the FDA’s interpretation of its labeling authority in which it claims to not have authority to require labeling for certain technologies was “adopted only amidst the politically charged debate over GM regulation and which departed significantly from the FDA’s own longstanding practice of requiring labeling in a variety of appropriate contexts to aid consumer decisionmaking.”¹⁷³

¹⁷⁰ Cathy Roheim Wessells, et al., *Product certification and ecolabelling for fisheries sustainability* FAO FISHERIES TECHNICAL PAPER 42, 2 (2001) available at <ftp://ftp.fao.org/docrep/fao/005/y2789e/y2789e00.pdf>.

¹⁷¹ Ian Angus, *Mislabeled food and the myth of ‘consumer sovereignty’*, CLIMATE AND CAPITALISM, available at <http://climateandcapitalism.com/?p=3134>.

¹⁷² Kysar, *supra* note 6, at 595, citing Martha C. Nussbaum, *The Good As Discipline, the Good As Freedom*, in ETHICS OF CONSUMPTION: THE GOOD LIFE, JUSTICE, AND GLOBAL STEWARDSHIP 312, 336 (David A. Crocker & Toby Linden eds., 1998).

¹⁷³ Kysar, *supra* note 6, at 594.

In support of this argument, people claim that when the FDA required labeling for irradiated food, it did so on the basis of consumer interest alone.¹⁷⁴

In *International Dairy Foods Association v. Boggs*, the Ohio case about rBST, the judge noted that “[l]ess than 70 of the 2,700 emails and letters sent to the ODA during this time period were in favor of the proposed Rule,” but “ODA Director Robert Boggs nevertheless adopted the Rule in May 2008,” suggesting that the Sixth Circuit believes that consumer interest should play a role in food labeling.¹⁷⁵

1. Labeling on the basis of consumer interest serves as a back-door way to undercut approval.

If irradiation labeling was required because of consumer interest, which a number of people argue, irradiation serves as an example of labeling on the basis of public interest working to prevent adoption of that technology. Arguably much more food would be irradiated if producers did not have to label it as irradiated.

Despite current efforts to maintain food safety, every year many people are sickened by microbial life on their food. “[B]ecause the symptoms are usually nonspecific (i.e., nausea, vomiting, and diarrhea), food poisoning often is mistaken for flu or other common ailment.”¹⁷⁶

Irradiation was determined to be a safe and effective way to reduce pathogen contamination on food, by the WTO, FDA, CDC, and other national and international bodies. People have been studying the effects of using ionizing radiation on food for decades.¹⁷⁷

¹⁷⁴ See, e.g., Nauheim, *supra* note 68, at 124-125 (“In 1986 . . . the FDA claimed authority . . . to mandate food labeling based on consumer interest alone [for irradiation].”).

¹⁷⁵ *International Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 634 (6th Cir. 2010).

¹⁷⁶ Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 685 (1998).

¹⁷⁷ See, e.g. A. Leonard Sheffner, et al., “*The Effect of Radiation Processing upon the In Vitro Digestibility and Nutritional Quality of Proteins*,” 22 J.FOOD SCI. 5, 455-461, (1957).

In 2010, the United States Government Accountability Office explained the reasons why it had been supporting ionizing radiation for ten years.

“According to the Centers for Disease Control and Prevention (CDC), pathogens such as *Salmonella*, *E. coli*, and *Listeria* cause an estimated 14 million cases of foodborne illnesses each year, resulting in about 60,000 hospitalizations and 1,800 deaths. Foodborne illness symptoms can range from mild gastroenteritis to life-threatening renal syndromes. The pathogens that account for much of the most severe foodborne illness can be greatly reduced by subjecting food to ionizing radiation, also known as food irradiation. For example, irradiation can eliminate as much as 99.999 percent of *E. coli* 0157, *Listeria*, and *Campylobacter*.”

The Centers for Disease Control and Prevention agrees, explaining that “[i]rradiation is a safe and effective technology that can prevent many foodborne diseases.” It explains that when food is irradiated, “disease-causing germs are reduced or eliminated, dangerous substances do not appear in foods, and the nutritional value of the food is essentially unchanged.” According to the CDC, “[t]he safety of irradiated foods has been endorsed by the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC) and by the Assistant Secretary of Health, as well as by the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA).”

Irradiation can be used to “control insects and microorganisms along with extending the shelf-life of fruits and vegetables and reducing dependence on refrigeration. . . . Since 1963, FDA has approved irradiation for wheat (1963), canned bacon (granted in 1963 but revoked in 1968), potatoes (1965), spices and dry vegetable seasonings (1983), dry or dehydrated enzyme preparations (1985), pork (1985), fresh fruits (1986), dry or dehydrated aromatic vegetable

substances (1986), poultry (1990) and beef (1997). Approvals have been granted for the purpose of disinfesting insects, decontamination, extending shelf-life, delaying maturation and controlling illness-causing microorganisms.”¹⁷⁸

However, in the United States, very little food is irradiated. As of 2007, only about 0.005 percent of fruits and vegetables and 9.5 percent of spices consumed in the United States were irradiated, and “spices, shell eggs, fruits and vegetables account for virtually all the food irradiation done in the United States.”¹⁷⁹ In 2001, one source noted that “[p]oultry irradiation has been approved for nearly 10 years, yet the rate of irradiation for consumer poultry is a paltry 0.2%! This seems particularly incredible given the scope of economic losses attributable to *Salmonella* (an estimated \$2.4 billion), and the relative lack of expense required to irradiate food.”¹⁸⁰

Case law indicates that although some United States companies have offered food irradiation, problems have arisen due to lack of consumer acceptance of irradiated food. In a shareholder’s class action suit, the record demonstrated that a food irradiation company in the United States had plants “generally operating at approximately 2%-3% of capacity” and that “the company was actually irradiating meat at no charge in an effort to introduce the product into the market.”¹⁸¹

Current laws require irradiated food to be labeled as such. This may have happened because some people worry that exposing food to radiation is dangerous. In general, radiation has very dangerous connotations. Atomic bombs, Chernobyl, the recent atomic reactor problems

¹⁷⁸ Matthew Freedman, *Food Irradiation: Too Many Risks, Too Few Benefits*, Electronic Book.

¹⁷⁹ 72 F. R. 64, 16297 (Apr. 4, 2007).

¹⁸⁰ Prejean, *supra* note 71.

¹⁸¹ *In re Surebeam Corp. Sec. Litig.*, 03 CV 1721JM(POR), 2005 WL 5036360 (S.D. Cal. Jan. 3, 2005).

in Japan, and radiation poisoning are some things that people associate with radiation. When considering radiated food, some people question whether the food will become radioactive.

In general, the fact that irradiation slows the ripening process should not be enough to require labeling. Given the fact that labeling means no irradiation, this interest of banana bread makers may need to be weighed against the interest of other consumers in having bananas that do not spoil as quickly, and the interests of everyone with a stake in preventing illness from microorganisms on bananas.

2. When people start trying to weigh the factors for food labeling, they sometimes bring in ones that make no sense.

The labeling of rBST is a good example. Judge Leval's dissent argues that Vermont had valid concerns about rBST with relation to "human and cow health, fears for the survival of small dairy farms, and concerns about the manipulation of nature through biotechnology." With the exception of his claim about manipulating nature, these concerns also come up with the use of any hormones in any food animal.

Research does show that rBST changes the milk in certain minor ways,¹⁸² but similar effects have been shown in milk treated with other hormones.¹⁸³ Similarly, rBST affects cows' life quality in some ways, but so do other hormones. This analysis suggests that the reasons such a fuss has been made about rBST is based mostly on the fact that it was genetically modified. Although, perhaps much weight was given to "fears for the survival of small dairy farms." Because that is certainly how food labeling decisions should be determined.

¹⁸² S.S. Epstein, *Unlabeled milk from cows treated with biosynthetic growth hormones: a case of regulatory abdication*, 26 INT'L. J. HEALTH SERV. 1, 173-85 (1996) ("Levels of insulin-like growth factor-1 (IGF-1) are substantially elevated and more bioactive in the milk of cows hyperstimulated with the biosynthetic bovine growth hormones rBGH, and are further increased by pasteurization.").

¹⁸³ A.Q. Talafha, et al, *The effect of estrus synchronization treatments on somatic cell count of transitional-anestrus Awassi ewes' milk*, 41 TROP. ANIM. HEALTH PROD. 2, 161-70 (Feb. 2009).

Similarly, some people argue against irradiation because, “given that irradiation enables meat and produce to be shipped across greater distances than current handling and processing technologies allow, some opponents fear that irradiation will further the erosion of local agricultural production and regional food security.”¹⁸⁴ This type of argument about possible societal effects should have no or extremely little weight in determining whether food should be labeled.; it should not be determinative.

3. Labeling may suggest that labeled foods are better or safer.

When producers label their food, “not produced with this technology,” the fact that they go out of their way to inform consumers this suggests that their foods are better or safer. This is not always the case.

For example, depending on how they are made, genetically engineered foods might be made with less pesticides or insecticides. If a variety of wheat was genetically engineered to be resistant to infection by the fungus *fusarium graminearum*, that wheat would likely have lower concentrations of the toxin produced by *fusarium*. Wheat is tested for concentrations of that toxin, but some minimal level is allowed in. Should that hypothetical genetically modified food be able to be labeled as “this wheat is genetically engineered to be less likely to contain x, a toxin that causes y problems?”

4. Consumer desires for labeling may not be based on accurate or complete information.

Consumer desires for labeling are not necessarily going to be based on accurate information. Some people are passionate about their food, but they are not always educated in science. Thanks to the internet, a great deal of incorrect information is easily spread about food technologies. Whereas in the past, the FDA could read the laboratory results and weigh the

¹⁸⁴ Kysar, *supra* note 6, at 592.

scales and determine whether or not a technology or food process was safe enough for consumption to the best of their ability, now consumers have access to some of that information at their fingertips, and they are easily able to second-guess the FDA's determinations and share information and misinformation with others.

With irradiation, one research paper suggested that there was increased likelihood of a type of cancer that developed in mice fed high amounts of a chemical that develops in irradiated food. People opposed to irradiation who read this article cite it as proof irradiation causes cancer.

The transcript from a Living on Earth broadcast from June 29, 2007 explains some reasons people argue in favor of labeling for radiated foods. The scientist interviewed, Dr. Urvashi Rangan, suggested that the fact that industry would prefer not to label irradiated food or use term like "cold pasteurization" means that industry has "something to hide." Dr. Rangan also described a study linking a radiation induced chemical to cancer, claimed that irradiation would result in spoiled meat being "zapped and then sold," and explained that irradiated meat tastes like "singed hair" or "wet dog hair."

Food approval decisions are so much more complicated than finding one researcher who found that one byproduct of a food processing technology can cause cancer. Irradiation is different than other food technologies and can affect food differently. Deciding whether companies should be permitted to use ionizing radiation to sterilize their food is complicated. (Although, all reputable bodies to have considered the question conclude that it should be permitted, as described above.)

According to a recent GAO report, the FDA is concerned about evidence that furans are formed when food is irradiated. Furans are generally considered carcinogenic. These seems like

a legitimate concern, but evidence shows that furans are also often produced in similar amounts in foods that are heat processed, along with other contaminants such as acrylamide and chloropropanols.¹⁸⁵ The science is not simple: irradiation not only creates furan, but it also degrades it.¹⁸⁶ Furan's boiling point is close to room temperature, so this means that if furan permeable packaging is used, levels of furan in heat or irradiation processed food decrease over time.¹⁸⁷

5. Individuals may be biased against novelty.

Heating meat to certain temperatures reduces the risk of dying from microorganisms in the meat.¹⁸⁸ However, perhaps initially people met this idea with resistance. Some food processing technologies people now regularly accept, such as pasteurization and microwave ovens, initially met resistance from people concerned about the effects such processing might have on the food.¹⁸⁹

Consumers are more likely to fear new technologies that have not proven themselves over the test of time. However, many food innovations represent steps forward in terms of improving health and safety, and merely because a food technology is new does not mean that it is more dangerous than food technologies that are older.

6. There will always be something else consumers want to know about their food.

¹⁸⁵ See, e.g., Thomas Wenzl, et al., *Review, Analysis of heat-induced contaminants (acrylamide, chloropropanols and furan) in carbohydrate-rich food*, 389 ANALYTICAL AND BIOANALYTICAL CHEM. 1, 119-137 (2007); Xuetong Fan, *Impact of Ionizing Radiation and Thermal Treatments on Furan Levels in Fruit Juice*, 70 J. OF FOOD SCI. 5, e409–e414 (2005).

¹⁸⁶ Xuetong Fan & Christopher H. Sommers, *Effect of Gamma Radiation on Furan Formation in Ready-to-Eat Products and their Ingredients*, 71 J. OF FOOD SCI. 7 c407-c412 (2006); Fan, *supra* note 189 at e409–e414.

¹⁸⁷ Fan & Sommers, *supra* note 190 at c407-c412.

¹⁸⁸ See, e.g., Christine Faille, *Injury and Lethality of Heat Treatment of Bacillus cereus Spores Suspended in Buffer and in Poultry Meat*, 60 J. FOOD PROTECTION 5, 544-547 (May 1997).

¹⁸⁹ Hoban, *supra* note 154.

The FDA has explained that it is more important to limit the information that is required on labels in order to permit people to find what is important rather than clutter labels with more information than people can handle.¹⁹⁰ Given the complicated food system, there are almost infinite numbers of things that people in theory could want to know about their foods. As the majority in *International Dairy Foods Ass’n v. Amestoy* suggested, next people may want mandatory labeling for the type of grain fed their cattle, or the date on which it was slaughtered. One person has sued to require labeling for whether the cattle fell down before it was killed.¹⁹¹

Should the decades of dispute about genetically engineered food, irradiation, and other technologies mean that the FDA should mandate labeling? These are the most pressing concerns of food labeling activists, but those people at places like Center for Science in the Public Interest do not want to lose their jobs. They will come up with something else that consumers have a right to know.

If public interest is our determining factor, what if a food company hires people to collect signatures that their technology matters? How many signatures are needed to show that a food attribute falls within this “right to know” category?

For another example, different canning technologies result in different amounts of nutrient loss. Should this be material? Or can the fact that they are probably all approximately the same be sufficient? What if a food company invests a lot of money to refurbish its factories with a new canning method that slightly reduces the amount of nutrient loss? Should they be able to recover their cost?

Some food is colored by cochineal, which is derived from a bug. It is used as a food coloring agent, and because it is derived from an organism, it fits into some consumers’ desires

¹⁹⁰ See, e.g., Degnan, *supra* note 17, at 54, citing 58 F.R. 2079, 2107 (Jan. 6, 1993).

¹⁹¹ *Baur v. Veneman*, 352 F.3d 625 (2d. Cir. 2003).

for “natural” coloring, so its use has been increasing lately. Should people who care about not eating bugs be able to mandate that all natural colors, flavors, etc., list what they are derived from? Or maybe just ones that are derived from bugs?

What about how far the food has traveled? “The more food miles fruits and vegetables have clocked up, the more their vitamin content is reduced.”¹⁹² Should each bag of apples be labeled with the GPS coordinates of the tree the apples came from?

7. Process Labeling imposes unnecessary costs.

To require labeling for processes would require producers to keep processed and not-processed products separate. Currently, spice manufacturers have to keep track of which spices they sterilize by fumigation with chemicals, and which spices they sterilize with radiation. By mandating labeling for differences which ultimately do not affect consumers, process labeling laws can impose unnecessary costs.

IV. Conclusion

Every food has a very long story, and many chapters in that story include information a consumer reasonably might want to know. Food labeling agencies have tried to balance the needs of consumers to know information about products with many other interests. A label full of text would be overwhelming and unhelpful. Even if each food were merely affixed with a barcode that could pull up all the details of the food’s history for interested consumers, any benefits of such a scheme would probably not outweigh the burdens imposed on producers by having to keep track of all the things a consumer might want to know.

Second, agencies are better able to perform risk assessments, because delegating to consumers the responsibility for deciding whether a food technology or other aspect of food is safe may be more likely to result in an incorrect assessment. Consumers do not usually have

¹⁹² FELICITY LAWRENCE, NOT ON THE LABEL (2004).

access to all of the scientific information that agencies have access to, and even if they have access to that information, consumers are often uneducated in science and thus easily swayed by arguments that do not make sense scientifically. These reasons, among others, support the idea that agencies rather than consumers generally should decide whether labeling for food processing technologies should be mandatory.

However, a harder question is whether the government can stop producers from voluntarily labeling their food as having been produced – or not produced – by a certain technology. With genetically modified foods in general, and specifically including milk from cows treated with rBST, initially the FDA suggested that labeling for the absence of the processing method could be misleading. First, all food has been genetically modified, and all milk contains BST. Second, since historically agencies have not mandated process labeling when no difference exists between the products, such labeling suggests that there is a difference between the products.

Additionally, voluntary labeling for the absence of a food processing technology can effectively label food that is processed, by negative implication. When labeling is voluntary, if a food characteristic matters to consumers, competition will lead to labeling.¹⁹³ A number of people are beginning to see voluntary labeling for the absence of a production method as effective for allowing consumers to choose to avoid those methods, rather than fighting for a consumer right to mandate labeling:

Rather than force labeling on [companies producing food using new technologies], the food industry ought to be free to advertise to customers—by label or any other means—how their product is produced. Food manufacturers

¹⁹³ *The Firm's Voluntary Labeling Decision*, 8, in Elise Golan, et al., *Economics of Food Labeling*, AGRICULTURAL ECONOMIC REPORT NO. 793, (Jan. 2001), available at <http://www.ers.usda.gov/publications/aer793/AER793.PDF>.

will soon discover whether a label hurts or hinders sales. Ultimately, consumers will drive labeling decisions¹⁹⁴

Some conclude that government agencies should not have the ability to restrict voluntary labels.

What consumers infer by the presence or absence of a label should not be the purview of the federal government. It's one thing for the FDA to protect consumers from fraud, but it's quite another to dictate whether true claims can or cannot appear on packaging. . . . It's long past time that food manufacturers are allowed to label their products according to consumer preference rather than bureaucratic whim.¹⁹⁵

Should voluntary labeling for the absence of a production method not be permitted if it leads to manufacturers not being able to use certain food production technologies that, according to all people most educated on the costs and benefits of the technology, have significant benefits for society as whole? (This requires the assumption that the production does not materially change the product; if it did, the use of the production would require labeling.)

This highly paternalistic idea of not allowing voluntary absence of technology labeling is unlikely to be accepted. Right-to-know activists would challenge any analyses of what technologies would benefit society as a whole, and many people like being able to choose to support certain production technologies or the absence of technologies that producers voluntarily label.

When the FDA explained its decisions not to require labeling for cloned foods and genetically modified foods, it mentioned as a factor in its decisions the fact that they are both just the most recent step in a continuum of food technologies. It is hard to draw the line between

¹⁹⁴ Diane Katz, *GM Salmon: Swimming Against the Regulatory Tide*, THE FOUNDRY, Oct. 26, 2010, available at <http://blog.heritage.org/?p=45534>.

¹⁹⁵ *Id.*

cloning technology and its precursors forms of assisted reproduction. Similarly, those who are up in arms about genetic modification have to realize that more crude forms of the same thing – from the corn hybrids that started the green revolution to radiation-induced mutagenesis of watermelons, to make them seedless – had been occurring for a long time, without any consequences – or labeling. Should it matter that the most recent forms of radiation technology, also represent the most recent step in a continuum of radiation technology?

Some people who are upset by the federal government's choices in labeling and other food issues argue that control of food should be local. One town in Maine declared itself free from some state and federal regulations about food.¹⁹⁶ Because “federal and state regulations impede local food production and constitute a usurpation of our citizens’ right to foods of their choice,”¹⁹⁷ the food ordinance exempts producers of local foods from licensure and inspection requirements when the food is sold by the producer directly to consumers at, for example, farmers’ markets and roadside stands.¹⁹⁸

Labeling food technologies is complicated, and maybe the various decisions the federal government has made cannot be explained in a simple way. This paper has failed to make sense of the varying decisions, or even to come up with a possible way of making future decisions. For the FDA, its application of the material difference standard seems to have resulted in good choices most of the time.

¹⁹⁶ Amy Halloran, *Maine Town Declares Food ‘Sovereignty’*, FOOD SAFETY NEWS (Mar. 10, 2011), <http://www.foodsafetynews.com/2011/03/maine-town-declares-food-sovereignty/>.

¹⁹⁷ *Id.*

¹⁹⁸ *Local Food and Community Self-Governance Ordinance; Town of Sedgwick, Maine, 2*, available at <http://www.sedgwickmaine.org/images/stories/local-food-ordinance.pdf>.